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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/713,598      | 11/15/2000  | George Mamo          | P-9580.00           | 3041             |

27581 7590 10/20/2003  
MEDTRONIC, INC.  
710 MEDTRONIC PARKWAY NE  
MS-LC340  
MINNEAPOLIS, MN 55432-5604

EXAMINER

MATTHEWS, WILLIAM H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3738

DATE MAILED: 10/20/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/713,598

Applicant(s)

MAMO ET AL.

Examiner

William H. Matthews (Howie)

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-14 and 16 is/are rejected.
- 7) ☒ Claim(s) 5 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Claim Objections***

Claim 13 is objected to because of the following informalities: claim 13 recites "anchoring" but is unclear as to what element is anchored. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1,3,4,7-12,14,16 rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf US PN 4,512,351 in view of Moumane et al. US PN 5,957,965.

Pohndorf discloses in figures 2 and 9-11 a method of minimally invasive implantation of an electrical stimulation lead in the spinal cord of a patient comprising the steps of implanting a 6-7 French dilator 20, 17 gauge needle 46, and a stimulation lead 10. With regard to claim 14, Pohndorf discloses a validation step in lines 43-50 of col. 6. With regard to claims 3-4, it is well known in the art of surgery to use general or local anesthetics. Pohndorf lacks the express written disclosure of utilizing the device and method at the sacrum for pelvic floor disorders. Moumane et al. teaches in columns 2-4 implantation of an electrical stimulation lead in the spinal chord at the

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sacrum in order to stimulate sacral nerves and treat pelvic floor disorders such as fecal or urinary control.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the method disclosed by Pohndorf for applications at the sacrum as taught by Moumane et al. and to use general or local anesthetics as is known in the art in order to stimulate sacral nerves and treat pelvic floor disorders such as fecal or urinary control.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf US PN 4,512,351 in view of Moumane et al. US PN 5,957,965 as applied to claim 1 above, and further in view of Knuth US PN 5,484,445.

The method disclosed by Pohndorf and modified by Moumane et al. comprises the steps of claim 13 but lacks the express written disclosure of a suture anchor. Knuth teaches in abstract and figures an anchor system for sacral stimulation leads comprising a suture anchor in order to maintain position of the stimulation lead.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Pohndorf as modified by Moumane et al. by including the step of using a suture anchor as taught by Knuth in order to maintain position of the stimulation lead.

***Allowable Subject Matter***

4. Claims 5 and 15 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Tue-Fri 8:00-6:30 (Every Monday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM  
October 17, 2003

  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700